

# EXHIBIT CC

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1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3                   CHARLESTON DIVISION

4                   -   -   -  
5       IN RE: ETHICON, INC. PELVIC       :MDL NO. 2327  
6       REPAIR SYSTEM, PRODUCTS       :  
7       LIABILITY LITIGATION       :VOLUME II  
8                   :

9                   THIS DOCUMENT RELATES TO ALL CASES AND  
10                  VARIOUS OTHER CROSS-NOTICED ACTIONS  
11                  CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

12                  -   -   -  
13                  January 8, 2014

14                  -   -   -  
15                  Transcript of the continued deposition of  
16       THOMAS A. BARBOLT, Ph.D., called for Videotaped  
17       Examination in the above-captioned matter, said  
18       deposition taken pursuant to Superior Court Rules of  
19       Practice and Procedure by and before Michelle L.  
20       Gray, a Certified Court Reporter, Registered  
21       Professional Reporter, and Notary Public, at the  
22       offices of Riker Danzig Scherer Hyland & Perretti  
23       LLP, Headquarters Plaza, One Speedwell Avenue,  
24       Morristown, New Jersey, commencing at 9:07 a.m.

25                  -   -   -  
26                  GOLKOW TECHNOLOGIES, INC.  
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1 the '97 time frame or so, and then I think the  
2 510(k) approval was in early 1998.

3 Q. And the information that you list in  
4 response to the degradation designation begins in  
5 1964; is that right?

6 A. Yes, that's correct.

7 Q. And it runs in chronological order  
8 all the way up until 2007, right?

9 A. Yes, that's correct.

10 Q. Why did you include studies that  
11 predated the TVT?

12 A. Well, the material used to  
13 manufacture TVT mesh is Prolene polypropylene  
14 filaments. And a great deal of work was done in the  
15 mid '60s and beyond, demonstrating biocompatibility  
16 of that product and essentially received FDA  
17 approval.

18 Q. What is an NDA?

19 A. An NDA is a new drug application.  
20 And at the time of the development of Prolene  
21 suture, polypropylene sutures were considered drugs.

22 Q. And did Ethicon go through a new drug  
23 application in order to have FDA approve the  
24 polypropylene suture that's now used in TVT mesh?

25 MR. THORNBURGH: Objection; beyond

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1 the scope.

2 THE WITNESS: Yes.

3 BY MR. THOMAS:

4 Q. And the first five studies in your  
5 degradation section are studies submitted to the FDA  
6 in connection with the Prolene suture NDA, correct?

7 A. That's correct.

8 Q. And let's talk about those briefly.  
9 Study of tissue reaction to the colorless and  
10 pigmented monofilament polypropylene suture in the  
11 rat, rabbit, and the dog.

12 Just tell me briefly what those  
13 studies are.

14 A. These were tissue reaction studies in  
15 three species of animals, with colored and  
16 non-colored suture, looking at tissue reaction over  
17 time.

18 Q. And how long were those studies?

19 A. The rat study was two years. That's  
20 the lifetime of a rat.

21 The dog study was two years. And the  
22 rabbit study was 90 days.

23 Q. And are those considered long-term  
24 studies?

25 A. The two-year rat as a lifetime study

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1 is certainly a long-term study, as with the dog  
2 study of a two-year duration.

3 Q. And what's the purpose of doing a  
4 tissue reaction study to a polypropylene suture in  
5 an NDA?

6 A. So for the purposes of a suture, the  
7 most important thing that needs to be determined is  
8 the tissue reaction of the material over time.

9 Q. And you have reviewed the tissue  
10 reaction studies from the NDA?

11 A. Yes.

12 Q. And are the tissue reaction findings  
13 for the polypropylene suture approved by the FDA  
14 similar to the findings that you have reviewed with  
15 respect to Prolene mesh?

16 MR. THORNBURGH: Objection to the use  
17 of the word, approved, as well as outside the scope  
18 of his designation.

19 THE WITNESS: The tissue reaction is  
20 very similar.

21 BY MR. THOMAS:

22 Q. Okay. And you understand that in  
23 order for Ethicon to be able to market this  
24 polypropylene suture, known as Prolene suture, the  
25 FDA had to approve the NDA?

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CERTIFICATE

I HEREBY CERTIFY that the witness was  
duly sworn by me and that the deposition is a true  
record of the testimony given by the witness.

It was requested before completion of  
the deposition that the witness, THOMAS A. BARBOLT,  
Ph.D., have the opportunity to read and sign the  
deposition transcript.

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MICHELLE L. GRAY, a Registered  
Professional Reporter, Certified  
Shorthand Reporter and Notary Public  
Dated: January 16, 2014

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